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| APPLICATION NO.                  | FILING DATE                     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|---------------------------------|----------------------|---------------------|------------------|
| 10/601,280                       | 06/20/2003                      | Helmut Muckter       | MUCKTER-2           | 6448             |
|                                  | 7590 04/27/200<br>IEREISEN, LLC | ,                    | . EXAMINER          |                  |
| 350 FIFTH AV                     | •                               |                      | WILLSE, DAVID H     |                  |
| SUITE 4714<br>NEW YORK, NY 10118 |                                 |                      | ART UNIT            | PAPER NUMBER     |
| ŕ                                |                                 |                      | 3738                |                  |
|                                  |                                 |                      |                     |                  |
| SHORTENED STATUTOR               | Y PERIOD OF RESPONSE            | MAIL DATE            | DELIVERY MODE       |                  |
| 2 MONTUS                         |                                 | 04/27/2007           | DADED               |                  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|   | Application No.   | Applicant(s)    |  |  |  |  |
|---|---|-----------------|--|--|--|--|
| Office Action Summers   | 10/601,280  | MUCKTER, HELMUT |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit        |  |  |  |  |
|   | Dave Willse   | 3738            |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |                 |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                 |  |  |  |  |
| Status  |   |                 |  |  |  |  |
| 1) Responsive to communication(s) filed on 01 Ma  | arch 2007   |                 |  |  |  |  |
| _   |   |                 |  |  |  |  |
|   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                 |  |  |  |  |
|   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                       |                 |  |  |  |  |
|   |   |                 |  |  |  |  |
| Disposition of Claims   |   |                 |  |  |  |  |
| 4) Claim(s) <u>4-6,8,10-15,17,19-22 and 24</u> is/are pe  |   |                 |  |  |  |  |
| 4a) Of the above claim(s) is/are withdraw   | n from consideration.   |                 |  |  |  |  |
| 5) ☐ Claim(s) is/are allowed.   |   |                 |  |  |  |  |
| 6) Claim(s) <u>4-6,8,10-15,17,19-22 and 24</u> is/are rej   | ected.  |                 |  |  |  |  |
| 7) Claim(s) is/are objected to.   |   |                 |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |   |                 |  |  |  |  |
| Application Papers  |   |                 |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |   |                 |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |                 |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                 |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |                 |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                 |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                 |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                 |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |   |                 |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |                 |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |                 |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |   |                 |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |                 |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |                 |  |  |  |  |
| the diagoned detailed emice detion for a list of the certified copies not received.   |   |                 |  |  |  |  |
|   |   |                 |  |  |  |  |
| Attachment(s)   |   |                 |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date  |   |                 |  |  |  |  |
| <ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO/SB/08)</li> </ul>   | Paper No(s)/Mail Da  5) Notice of Informal Pa   |                 |  |  |  |  |
| Paper No(s)/Mail Date   | 6) Other:   |                 |  |  |  |  |

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In attempting to show support for previous revisions to the specification, the Applicant identifies certain locations in "the foreign priority document" but does not identify *which one* of the two foreign priority documents is being referenced; this deficiency must be corrected in response to the present Office action.

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The Applicant's other remarks have been considered. The amended preamble of claim 21 merely states the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations; therefore, "the preamble is not considered a limitation and is of no significance to claim construction" (MPEP § 2111.02, section II). The Applicant has not provided a definition, in a manner prescribed by MPEP § 2111.01, of the term "pump housing" (claim 21, line 3) so as to exclude the vascular connections of the applied prior art (amendments to claim 21 at lines 7 and 9). In fact, the Applicant's own invention encompasses suture rings and vascular prostheses as being part of the "housing" (claims 19, 21, and 24). And as noted previously, the term "integral" (e.g., claim 21, line 7) was held not to be limited to a fabrication of the parts from a single piece of metal, but was inclusive of other means of maintaining the parts fixed together as a single unit (In re Larson et al., 144 USPQ 347). "Integral" is sufficiently broad to embrace constructions united by such means as fastening and welding (In re Hotte, 177 USPQ 326). A "blood vessel" is defined as "any of the vessels through which blood circulates in the body" (Merriam Webster's Collegiate Dictionary, 10th edition: 1996) and is thus broadly interpreted relative to the present claims (MPEP § 2111). Moreover, such a feature is not a positively recited element of the instant invention, and blood vessel sizes vary widely in human beings and even more so in the animal kingdom. Therefore, it

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is thus not seen how the current claim language excludes pumps sized to be inserted within natural hearts (which themselves range in size).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17, 19-22, and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goldowsky, US 6,068,588. Figure 5 illustrates a pump housing including a casing 22 for accommodating an impeller 50, a first vascular connection 10a formed integral with element 22b, and a second vascular connection 10b formed integral with element 22c. The vascular connections 10a and 10b are constructed so as to be capable of direct attachment to a blood vessel through suturing (column 2, lines 18-20). Regarding claim 17: column 2, lines 33-36. Regarding claim 22, attention is directed to rotary motor 52 (Figure 5). Regarding claim 24, the inlet and outlet tubes 10a and 10b are viewed as vascular prostheses because they serve as elements of the cardiovascular system of a patient.

Claims 19-22 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jarvik, US 4,994,078. Figures 7 and 29 show a pump housing accommodating impeller blades **502** and having ends *capable* of direct attachment at two locations of a blood vessel. The inflow

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vascular graft or prosthesis **70** serves as one of the vascular connections and is constructed so as to be directly suturable to the blood vessel (column 13, lines 60-64), and the same is true for the outflow vascular graft or prosthesis **72** (column 13, lines 64-67).

Claims 8, 10-12, 19-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al., US 6,116,862, in view of Jarvik, US 4,994,078. The embodiment of Figure 3 possesses all the features set forth in current claim 21 except, possibly, for vascular connections constructed for attachment to the blood vessel through suturing. To install the embodiment of Figure 3 for interposition in a blood vessel via suturing to prosthetic vascular grafts mechanically affixed to respective inlet 12 and outlet 18 (a procedure well known in the art, as seen from the Jarvik patent discussed above) would have been obvious in order to replace diseased vascular tissue, to ensure a proper fit with inlet 12 and outlet 18, and/or to prevent tissue trauma potentially arising from mechanically connecting the natural blood vessel itself directly to inlet 12 and outlet 18, with the ordinary practitioner having been left to devise an appropriate implantation scheme and having been further motivated by the apparent suturing at ports 43 and 43a (Figures 2a and 2b) in the first illustrated embodiment and by the explicit reference to Jarvik in Rau et al. at column 1, lines 8-16. Regarding claim 10, the webs 53 and 54 are capable of housing cables for the transmission of electrical current, whether or not such was the intent; in fact, such a configuration would have been inherent because passage 17 (column 2, lines 47-48) of the first embodiment (Figure 1) does not exist in the embodiment of Figure 3.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. in view of Jarvik as applied to claim 21 above, and further in view of Chardack, US 4,957,504.

Rau et al. lack a second pump housing with an impeller and a motor. Chardack teaches two

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parallel pumps for effecting various types of synchronized pumping (column 5, line 54 et seq.). To similarly arrange a second blood pump in parallel with the first in the invention of Rau et al. would have been obvious in order to achieve various combinations of continuous or pulsatile flow and/or to simply provide a redundant pump as a backup, with further motivation having been provided by both references being directed to ventricular assist via rotary pumping.

Regarding claim 14, an adaptable connection device would have been obvious from the harness 78 of Chardack in order to facilitate control of the two pumps (Chardack: column 5, lines 54-62). Regarding claim 15, one of the motors is functionally *capable* of running in an opposite direction by reversing the polarity of its electric power source.

Claims 4-6, 19-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al., US 4,688,998. Figures 3 and 7-9, for example, illustrate all the elements except for suturable vascular connections. However, vascular prosthetic connections constructed for suturing would have been obvious, if not inherent, to one of ordinary skill in view of column 7, lines 10-12; column 9, lines 3-5 and 16-18; Figure 4; etc.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing

date of this final action.

proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or

Dave Willse

Primary Examiner

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